APV comments regarding 21 CFR Part 11 Reform
Electronic Record; Electronic Signatures; Public Meeting (FDA)

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss various topics concerning our regulations on electronic records and electronic signatures in part 11 (21 CFR part 11). FDA has begun to re-examine part 11 as it applies to all FDA-regulated products. We will consider the input from the public meeting and comments on the topics presented in this document as we evaluate potential changes to part 11.

DATES: The public meeting will be held on June 11, 2004, from 8 a.m. to 4:30 p.m. Submit written or electronic requests to speak plus a presentation abstract by May 12, 2004. Although written or electronic comments on the issues presented in this document will be accepted until July 9, 2004, to have your comments considered at the meeting, submit them by May 12, 2004.

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III. FDA's Objectives in Re-Examining Part 11

FDA's re-examination of part 11 includes the following objectives:

- To prevent unnecessary controls and costs, yet retain the objectives of the rule.
- To clarify the scope of part 11 (e.g., how it relates to other FDA regulations).
- To ensure that part 11 provides an adequate level of record security, authenticity, and integrity, and encourages innovation and technological advances.
- To further these objectives, we are seeking to accomplish the following:
- Identify areas where part 11 could be less prescriptive and detailed, and
- Clarify the relationship between part 11 and other FDA regulations (predicate rules) with respect to record and recordkeeping requirements.

IV. Topics for Discussion and Comment

FDA would like public input to assist with our re-examination of part 11. We invite discussion on the scope of part 11, risk-based approaches, validation, audit trails, record retention, record copying, and legacy systems. We present the following specific issues and questions for comment in the public meeting.

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	A. Part 11 Subpart A--General Provisions	
1	In the part 11 guidance document, we clarified that only certain records would fall within the scope of part 11. For example, we stated that under the narrow interpretation of its scope, part 11 would apply where records are required to be maintained under predicate rules or submitted to FDA, and when persons choose to used records in electronic format in place of paper format. On the other hand, when persons use computers to generate paper printouts of electronic records, those paper records meet all the requirements of the applicable predicate rules, and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be ``using electronic records in lieu of paper records'' under Sec. 11.2(a) and (b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11. We are interested in comments on FDA's interpretation of the narrow scope of part 11 as discussed in the part 11 guidance and whether part 11 should be revised to implement the narrow interpretation described in the guidance.	Some clarification would be helpful, but the scope should be described very clearly in order to avoid a rediscussion as they had been in the past years. The Guidance for Industry Part 11, Scope and Application, August 2003 should be the basic document for implementation.
2	We are interested in comments on whether revisions to definitions in part 11 would help clarify a narrow approach and suggestions for any such revisions.	Definition of electronic records in terms of process risk and regulatory requirements. Software should not be regarded as electronic records.
3	In the part 11 guidance we announced that we did not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 in the manner described in the part 11 guidance. We emphasized that records must still be maintained or submitted in accordance with the underlying predicate rules, and the agency could take regulatory action for noncompliance with such predicate rules. We are interested in comments on the need for clarification in part 11 regarding which records are required by predicate rules and are therefore required to be part 11 compliant?	A process oriented approach is needed to define which data, raw data or derived data, are data used in ERs.

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	B. Part 11 Subpart B--Electronic Records	
1	As mentioned previously, the part 11 guidance identified four areas where we do not intend to take enforcement action under the circumstances described in the part 11 guidance, including the validation, audit trail, record retention, and record copying requirements of part 11. The part 11 guidance further recommends that decisions on whether or not to implement part 11 requirements on validation, audit trail, record retention, and record copying should be based on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. We are interested in comments on whether there are other areas of part 11 that should incorporate the concept of a risk-based approach, detailed in the part 11 guidance (e.g., those that require operational system and device checks).	The definition of electronic records itself should be based on a risk based approach.
2	Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?	No.
3	Under the current part 11, the controls that apply to electronic records that are maintained also apply to electronic records that are submitted to FDA. Should the requirements for electronic records submitted to FDA be separate from electronic records maintained to satisfy predicate rule requirements?	1. yes, separating between submission documents and predicate rules documents could be necessary, e.g. requirements for new drug applications (NDA) should not be used for ERs in general. Audit trails for the generation of submission documents should not be required (draft version). 2. draft-versions of documents should not be treated as ERs
4	The controls for electronic records in subpart B distinguish between open systems (an environment where system access is not controlled by persons who are responsible for the content of electronic records that are on the system) and closed systems (an environment where system access is controlled by persons who are responsible for the content of electronic records that are on the system). Should part 11 continue to differentiate between open systems and closed systems?	Yes, the current definition and requirements are still necessary.

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5	For individual controls in subpart B, we request comments on the following: 1. The part 11 guidance identified validation as one of the four areas where we intend to exercise enforcement discretion in the manner described in the guidance. Should we retain the validation provision under Sec. 11.10(b) required to ensure that a system meets predicate rule requirements for validation?	Validation for requirements arising from 21 CFR Part 11 should be defined as a general requirement with reference to current validation requirements. No additional requirements should be defined here.
	2. The part 11 guidance identified record retention and record copying requirements as areas where we plan to exercise enforcement discretion in the manner described in the part 11 guidance. Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention? What requirements would preserve record security and integrity and ensure that records are suitable for inspection, review, and copying by the agency?	To ensure that records are suitable a validated process of copying and migration should be accepted to be sufficient.
	3. Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?	No, not in general. This should be based on a risk based approach.
	4. Section 11.10(k) requires appropriate controls over systems documentation. In light of how technology has developed since part 11 became effective, should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?	Configuration management, document management and version control are absolutely necessary. But they are already defined in current validation requirements and good documentation practices. So no further requirements should be defined here. The current formulation of section 11 .10(k) is an additional requirement which should not be part of 21 CFR Part 11.

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	C. Part 11 Subpart C--Electronic Signatures	
1	Within the context of subpart C, we would like interested parties to address the following: Section 11.10(d) requires that system access be limited to authorized individuals, but it does not address the handling of security breaches where an unauthorized individual accesses the system. Should part 11 address investigations and followup when these security breaches occur?	The handling of security breaches is taken to be already included in limiting system access to authorized individuals.
	D. Additional Questions for Comment	
1	What are the economic ramifications of modifying part 11 based on the issues raised in this document?	There will be a positive impact, because the level of compliance can be set to an appropriate level which balances both quality and economical issues.
2	Is there a need to clarify in part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules? If so, how could this distinction be made?	It should be possible to define electronic records within a process oriented approach, see also A2 and A3.
3	In what ways can part 11 discourage innovation?	If there are too much general requirements which do not fit to the individual situation. If no migration of data is possible with deletion of the original data. If draft documents are defined as ERs and users prefer to deal with paper records. a to broad definition of the term electronic record (see A2, A3, B1)
4	What potential changes to part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?	1. As a minimal requirement the narrow interpretation of the scope of 21 CFR Part which is used in the Guidance for Industry, August 2003, should be used. 2. More process orientation 3. the use of a risk based approacht 4. The definition of electronic records itself should be based on a risk based approach.(B1)

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5	What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?	First a risk based approach of process risks and then an analysis of technical risks should be performed.
6	The part 11 guidance announced that the agency would exercise enforcement discretion (during our re-examination of part 11) with respect to all part 11 requirements for systems that otherwise were operational prior to August 20, 1997 (legacy systems), the effective date of part 11. What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997? Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?	Combining the narrow interpretation of the scope of 21 CFR Part 11 and the risk based approach can help to eliminate concerns regarding legacy systems. In addition a process oriented approach of ERs could help.
7	Should part 11 address record conversion?	Yes, see B 5.2
8	Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?	A process oriented approach is needed to define which data are data used in ERs. In general 21 CFR Part 11 should provide requirements which are independent from technologies .

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